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2.01: General Provisions

- (1) <u>Scope and Purpose.</u> 114.5 CMR 2.00 governs the disclosure of hospital case mix and charge data submitted by hospitals to the Division of Health Care Finance and Policy pursuant to 114.1 CMR 17.00. The purpose of 114.5 CMR 2.00 is to safeguard the privacy rights of case mix data subjects while permitting limited access to such data where such access serves the public interest.
- (2) Effective Date. 114.5 CMR 2.00 shall be effective on July 20, 2009.
- (3) <u>Authority</u>. 114.5 CMR 2.00 is adopted pursuant to M.G.L. c.118G and M.G.L. c. 66A, the Fair Information Practices Act.

2.02: Definitions

As used in 114.5 CMR 2.00, the following words shall have the following meanings:

CMS. The federal Centers for Medicare and Medicaid Services.

Case Mix Data. Case specific, diagnostic discharge data which describe socio-demographic characteristics of the patient, the medical reason for the admission, treatment and services provided to the patient, and the duration and status of the patient's stay in the hospital. Case mix data includes the data elements specified in 114.1 CMR 17.03, the data specification manuals for Hospital Inpatient Data, Outpatient Observation Data, and Hospital Outpatient Emergency Department Data, and associated administrative bulletins. Case mix data do not include patient name or social security number. Case mix data include a unique health identification number (UHIN) encrypted by the Division from the patient's social security number and the Massachusetts Board of Registration in Medicine License Number for the physician for each significant procedure.

<u>Charge Data</u>. The full, undiscounted total and service specific charges billed by the hospital to the general public as defined in M.G.L. c.118G. Charge data includes the data elements specified in 114.1 CMR 17.03 and the data specification manuals for Hospital Inpatient Data, Outpatient Observation Data, and Hospital Outpatient Emergency Department Data, and associated administrative bulletins.

<u>Data Protection Committee</u>. An internal DHCFP committee comprised of staff members with clinical, technical, or legal expertise as designated by the Commissioner to review applications

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for case mix data and ensure that external releases of confidential data conform to Division policies and law.

Division. The Division of Health Care Finance and Policy established under M.G.L. c.118G.

<u>Deniable Data Elements</u>. Those data elements which either solely or in combination with other data elements jeopardize patient privacy and which will not be disclosed unless the Division determines that an applicant fulfills the requirements imposed by 114.5 CMR 2.03. Deniable data elements include medical record number, mother's medical record number, billing number, the Medicaid Recipient Identification Number (Claim Certificate Number), the UHIN, date of admission (registration or begin date), date of discharge (end date), date of birth, date(s) of significant procedures, UPN, Massachusetts Board of Registration in Medicine License Number, and patient street address. Additional deniable Emergency Department data elements include stated reason for visit and ambulance run sheet number.

<u>Level I Data</u>. Case mix data which includes all data elements with the exception of deniable data elements. Level I data may include, but is not limited to, the following summative data fields as determined by the Division: month and year of encounter, month and year of departure, length of inpatient stay, day(s) in hospital when surgery occurred; age of patient at one year intervals for patients one year or older; and age of patient at one week intervals (or other standard intervals) for patients less than one year old.

Level II Data. Case mix data which include Level I Data plus the UPN.

<u>Level III Data</u>. Case mix data which include Level I Data plus the UHIN, the mother's UHIN, an admission sequence number for each UHIN record, and may include days between stays for each UHIN record.

<u>Level IV Data</u>. Case mix data which includes Level I Data plus the UPN, the UHIN, the mother's UHIN, an admission sequence number for each UHIN record, and may include days between stays for each UHIN record. Level IV for Hospital Outpatient Emergency Department data also includes reason for visit. The unencrypted physician's Board of Registration in Medicine License Number is available as a separate companion file to Level IV through Level VI.

<u>Level V Data</u>. Case mix data which include Level IV Data plus the date of admission (registration or begin date), date of discharge (end date) and date(s) of significant procedures.

<u>Level VI Data</u>. Case Mix data which include all the deniable data elements identified in 114.5 CMR 2.02 except the Medicaid Recipient Identification Number and patient street address.

<u>UHIN</u>. A unique health identification number encrypted by the Division from the patient's social security number.

<u>UPN</u>. A unique physician number encrypted by the Division from the Massachusetts Board of Registration in Medicine License Number.

2.03: Procedures for Data Requests

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- (1) <u>General Requirements.</u> All individuals and agencies that request access to or use of case mix data shall submit a written application. The applicant must demonstrate a need for the data and for each deniable data element requested. The Division will release only those deniable data elements which it determines to be necessary to accomplish the applicant's intended use.
- (2) <u>Application Requirements</u>. All applicants for the data shall:
 - (a) specify the level of data requested.
 - (b) specify the purpose for which the data is being requested.
 - (c) contain a detailed project description or other specific use intended for the data:
 - (d) explain why the applicant needs any requested deniable data elements to accomplish its stated purpose;
 - (e) specify the applicant's qualifications to perform such research or accomplish the intended use; and
 - (f) specify security and privacy measures to be taken in order to safeguard patient privacy and to prevent unauthorized access to or use of such data.

(3) Application Review Procedures.

- (a) <u>Data Protection Committee</u>. The Data Protection Committee will review all applications for determination of approval. The Division will post all applications on the Division's website, except the applicant's proposed security and privacy measures and any other document that contains confidential information.
- (b) <u>Criteria for Approval</u>. The Division will approve an application if it determines that:
 - 1. the purpose for which the data is requested is in the public interest. Uses that serve the public interest include, but are not limited to: health cost and utilization analysis to formulate public policy; financial studies and analysis of hospital payment systems; utilization review studies; investigations of fraud and abuse; hospital merger analyses; health planning and resource allocation studies; epidemiological studies, including the identification of morbidity and mortality patterns, and studies of prevalence and incidence of diseases; and research studies and investigation of other health care issues;
 - 2. the applicant has demonstrated it is qualified to undertake the study or accomplish the intended use;
 - 3. the applicant requires such data in order to undertake the study or accomplish the intended use;
 - 4. the applicant can insure that patient privacy will be protected;
 - e. the applicant can safeguard against unauthorized use; and
 - 5. the applicant requires that any recipient or agent which processes data on behalf of the applicant agrees to the required assurances.
- (c) If the Division determines that the needs of an applicant can be satisfied by releasing fewer deniable data elements than the number of deniable elements contained in the requested level, the Division will authorize access to the level containing the fewest number of deniable data elements.

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- (d) <u>Data Review Board</u>. The Commissioner shall designate a Data Review Board to review applications for data that contains unencrypted physician Board of Registration in Medicine License Number available as a separate companion file to Level IV through Level VI. The Data Review Board will consist of the members of the Division's Data Protection Committee as well as external members invited to participate by the Commissioner, including: one representative of the Massachusetts Hospital Association, one representative of the Massachusetts Medical Society, one representative of a health plan and one representative from the business community. The Data Review Board will review and evaluate the impact of a requested data release containing unencrypted physician Board of Registration in Medicine License Number data. To accomplish this purpose, the Data Review Board shall meet at least quarterly for the review of research applications and related materials. The Data Review Board will review the potential impact on data subjects and in research involving comparisons of individual health care providers, prevent the dissemination of inaccurate provider profiles and the unauthorized use or disclosure of provider profiles. The Board will also review reports that identify physicians prior to publication pursuant to 114.5 CMR 2.04(3).
- (4) The Division will notify each applicant of its decision within 30 days of its receipt of a completed application. If the application is incomplete or if the Division determines that supplemental information is needed to make its decision, the Division may require such supplemental information and notify the applicant of its decision within 30 days of its receipt of such information.
- (5) The Division shall charge a fee to all persons and organizations requesting case mix and charge data. The fee may reflect the total cost of systems analysis, program development, and computer production costs incurred in producing the requested data, and postage. Applicants may also be required to furnish their own tape or other appropriate medium to the Division for processing. The fee may be waived in the following instances:
 - (a) requests by CMS or an agency of the Commonwealth;
 - (b) requests by researchers that can demonstrate that imposition of a fee would constitute a hardship.

2.04: Data Disclosure Restrictions

- (1) <u>Required Assurances</u>. All applicants shall make assurances that:
 - (a) data will be used only for the purpose stated in the request;
 - (b) no attempt will be made to use any data supplied to learn the identity of specific patients;
 - (c) no data containing deniable data elements organized by individual record of discharge will be released to any other person or entity except as specified in 2.04(2);
 - (d) no data organized by individual record of discharge will be released for combinations of six records or fewer, except as provided in 114.5 CMR 2.04(2)(a);

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- (e) no data using physician Board of Registration in Medicine License numbers will be released for combinations of ten records or fewer;
- (f) comparisons among provider profiles adjust for patient case-mix data and other relevant risk factors and control for provider peer groups when appropriate; and
- (g) the applicant can ensure that any recipient of data or agent which process data on behalf of the applicant will also make the required assurances.
- (2) <u>Permissible Disclosures</u>. Approved applicants:
 - (a) may release to a hospital the hospital's own case mix data for the sole purpose of verifying the accuracy of the hospital's data;
 - (b) may release a report or transfer or exchange data which contains only non-deniable data elements, provided the recipient makes the assurances provided in 114.5 CMR 2.04(1);.
 - (c) may release a report or transfer or exchange data which contains only Level II data elements provided that no data organized by individual record of discharge with a Unique Physician Number will be released for combinations of six records or fewer; and
 - (d) may release a summary study which aggregates multiple records organized by UHIN and which does not disclose the actual UHIN or any deniable data elements.
- (3) <u>Pre-publication approval</u>. An applicant must obtain prior approval from the Division to release certain reports to another person or entity. The Division will review the report to determine whether the privacy rights of any data subject would be violated by the release of the report. An Applicant must submit its report for prior approval if:
 - a. the report contains Level III, Level IV, Level V or Level VI data, including summary studies that aggregate multiple records organized by UHIN.
 b. the report identifies individual physicians. The applicant must submit to the Division a copy of the report or a proposal for a standard format for additional review by the Division's Data Review Board to determine whether the methodology is sound; whether the entire methodology for analyzing the data is disclosed in the report; whether the privacy rights of any data subject would be violated by such release; and whether the applicant's report meets the requirements in 114.5 CMR 2.04(1) (e) and (f). The Division will notify the Massachusetts Hospital Association, and Massachusetts Medical Society at least 30 days prior to authorizing release of reports that identify individual physicians.

2.05: Other Provisions

- (1) Other Government Agencies. The Division may release case mix data to:
 - (a) organizations under contract to the Division to undertake studies;
 - (b) other government agencies whose applications meet the criteria set forth in 114.5 CMR 2.03; and
 - (c) if the criteria set forth in 114.5 CMR 2.03 are met, the Division will not limit the right of the following entities to receive case mix data to the extent permitted by applicable laws and regulations:
 - 1. the Centers for Medicare and Medicaid Services;

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- 2. the Executive Office of Health and Human Services Office of Medicaid may receive case mix data pertaining to Medicaid patients and such case mix data may also include the Medicaid Recipient Identification Number; and
- 3. the Department of Public Health may receive data in order to perform studies concerning public health.
- (2) Other Disclosures. The Division or its agent may release draft reports or other analyses that contain or use confidential case mix and charge data for review and comment. If the Division or its agent provides a health care provider or other individual with a draft report or other analysis for review and comment, the contents of such report or the analysis contained in such report are confidential, and may not be disclosed without prior approval by the Division. All reports and analyses that contain or use case mix and charge data will remain confidential until such report or analysis is publicly disclosed by the Division.

(3) Administrative Bulletins

The Division may, from time to time, issue administrative bulletins to clarify its policy on substantive provisions of 114.5 CMR 2.00. In addition, the Division may issue administrative information bulletins which specify the information and documentation necessary to implement 114.5 CMR 2.00.

2.06 Sanctions

- (1) If an approved applicant fails to comply with any of the requirements and conditions for receiving case mix and charge data in 114.5 CMR 2.00, the Division may:
 - (a) deny access to case mix or charge data in the future;
 - (b) terminate current access to case mix or charge data; and/or
 - (c) demand and secure the return of all case mix and charge data.
- (2) Violations of 114.5 CMR 2.00 may also subject the violator to applicable statutory sanctions.

2.07 Severability

The provisions of 114.5 CMR 2.00 are severable. If any provision or the application of any provision is held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 114.5 CMR 2.00 or the application of such provisions.

REGULATORY AUTHORITY

114.5 CMR 2.00: M.G.L. c.118G and M.G.L. c. 66A.